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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/509,184
Filing Date: September 24, 2004
Appellant(s): SLOWEY ET AL.

Ted K. Ringsred
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 17, 2008 appealing from the Office action mailed October 16, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments after Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 1-14 and 17 under 35 U.S.C. 112, second paragraph as being indefinite.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,131,566	ASHURST et al.	10-2000
WO 00/53187	TROFAST et al.	09-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast et al. (WO 00/53187) in view of Ashurst et al. (US 6,131,566).

Applicants claim an aerosol composition comprising particles of formoterol, a propellant selected from 1,1,1,2-tetrafluroethane and 1,2,3,3,3-heptafluoropoprane and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer.

Determination of the scope and content of the prior art
(MPEP §2141.01)

Trofast et al. teach a pharmaceutical combination comprising formoterol and mometasone. Page 3, lines 14-18 teaches the composition further containing one or more pharmaceutically acceptable additives, diluents or carriers. Page 3, lines 22-27 teach that the preferred form of formoterol is the fumarate dihydrate salt and the preferred form of mometasone is the monohydrate of the furoate ester. Page 5, line 24 through page 6, line 11 teaches that the composition can be inhaled from a nebulizer, pressured metered dose inhaler, or as a dry powder from a dry powder inhaler. Trofast et al. also teach that a diluent or carrier such as lactose, dextran, mannitol or glucose can be added to the medicament. Trofast et al. also teach that the one or more ingredients are preferably in a micronized dry powder form having a particle size of less

than 10 microns. Page 6, lines 13-20 teach that when the system is a pressurized inhaler, the ingredients are preferably in micronized form and that it is suspended in a liquid propellant such as P134a (tetrafluoro-ethane) and P227 (heptafluoropropane). The propellants can also be used in combination with one or more surfactants or excipients, such as ethanol.

***Ascertainment of the difference between the prior art and the claims* (MPEP §2141.02)**

Trofast et al. do not teach coating the interior surface of the aerosol vial with a fluorocarbon polymer. It is for this that Ashurst et al. is joined.

Ashurst et al. teach a metered dose inhaler having all or part of its internal surfaces coated with one or more fluorocarbon polymers (abstract). Column 1, lines 50-63 of Ashurst et al. teach that some aerosol drugs tend to adhere to the inner surfaces of inhalers and that coating the interior surfaces can reduce the problem of adhesion or deposition on the can walls.

Finding of prima facie obviousness
***Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Ashurst et al. in the invention of Trofast et al. to make an aerosol composition comprising particles of formoterol, a propellant and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with

a fluorocarbon polymer. It is the position of the examiner that although the coated interior surfaces of Ashurst et al. is used for albuterol, the same holds true for drugs that adhere to the interior walls of aerosol vials. Because formoterol adheres to the interior wall of aerosol vials, it is reasonable for one of ordinary skill to look to the combined teaching of Trofast et al. and Ashurst et al. for a solution to the problem of undesired adhesion.

(10) Response to Argument

Appellants argue that the "diluent or carrier" is directed to the context of a DPI formulation and not as a bulking agent. This is not found convincing. Page 6, lines 13-20 teach that the ingredients can be adapted to be administered via a pressurized inhaler. It is the position of the examiner that the "ingredients", as taught, includes the composition as disclosed on page 3, lines 14-18, which includes one or more pharmaceutically acceptable additives, diluents or carriers.

Applicants also argue that the particle size of less than 10 microns is expressly directed to the active ingredients and thus not the carrier. This is also not found convincing. Page 6, lines 8-9 teach that a fraction of the carrier particles can be fine, i.e. preferably less than 10 microns. It is the position of the examiner that any and all particles sizes, including less than 1 micron falls within range taught by Trofast et al. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art", a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191

USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Johann R. Richter/

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Conferees:

/Konata M. George/

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